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AGENDA: Randomised, double-blind trial of dacarbazine with or without Genasense® (oblimersen, G3139) in advanced melanoma

Submission date	Recruitment status	[_] Prospectively registered
14/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/04/2019	Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.genta.com/agenda.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00518895

Secondary identifying numbers
GM307

Study information

Scientific Title
A multicentre, randomised, double-blind study of dacarbazine with or without Genasense® in chemotherapy-naïve subjects with advanced melanoma and low lactate dehydrogenase (LDH) (The AGENDA Trial)

Acronym
AGENDA

Study objectives
This study is being performed to prospectively determine whether dacarbazine plus Genasense® is significantly better than dacarbazine plus placebo in chemotherapy-naïve subjects with advanced melanoma and baseline lactate dehydrogenase (LDH) less than or equal to 0.8 x upper limit of normal (ULN). LDH is a biomarker strongly associated with improved outcomes in a recent trial of dacarbazine plus Genasense®.

Ethics approval required
Old ethics approval format

Ethics approval(s)
USA: The University of Texas, M.D. Anderson Cancer Center, Office of Protocol Review, approved in July 2007
France: The Salvator Hospital, Comite de Protection des Personnes Sud-Mediterranee I, Marseille, approved in October 2007

Other sites will also obtain ethics approval before recruitment of participants.

Study design
Phase III, multicentre, randomised (1:1), double-blind, placebo-controlled, parallel-group trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not currently available, please refer to the contact details below to request additional information.

Health condition(s) or problem(s) studied
Melanoma

Interventions
Protocol therapy is administered in 21-day cycles for up to 8 cycles.

Subjects in the dacarbazine plus Genasense® group receive Genasense® 7 mg/kg/day by continuous intravenous infusion beginning on Day 1 and continuing for 5 days (120 hours) plus dacarbazine 1,000 mg/m^2 as a 60-minute intravenous infusion immediately following the conclusion of the Genasense® infusion.

Subjects in the dacarbazine plus placebo group receive placebo (that is, locally available commercial 0.9% sodium chloride injection) by continuous intravenous infusion beginning on Day 1 and continuing for 5 days (120 hours) plus dacarbazine 1000 mg/m^2 as a 60-minute intravenous infusion immediately following the conclusion of the placebo infusion.

In both treatment groups, subjects who are responding or have stable disease after 8 cycles of therapy may, at the Investigator's discretion, continue that same therapy for up to 8 additional cycles.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Genasense® and dacarbazine

Primary outcome measure
Progression-free survival and overall survival

Secondary outcome measures
1. Response rate
2. Durable response rate
3. Duration of response
4. Safety

Follow-up every 2 months for up to 24 months from date of randomisation.

Overall study start date
01/07/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. At least 18 years of age, both males and females
2. Histologically confirmed diagnosis of melanoma
3. Progressive disease that is not surgically resectable, or metastatic Stage IV disease
4. Low LDH (defined as LDH less than or equal to 0.8 x ULN)
5. Chemotherapy naïve
6. Measurable disease
7. Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 1
8. At least 4 weeks and recovery from effects of major prior surgery or other therapy, including immunotherapy, radiation therapy, or cytokine, biologic or vaccine therapy
9. Adequate organ function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Prior cytotoxic chemotherapy, including regional perfusion, or prior Genasense® treatment
2. Primary ocular or mucosal melanoma
3. Bone-only metastatic disease
4. History or presence of brain metastasis or leptomeningeal disease
5. Significant medical disease other than cancer
6. Organ allograft

Date of first enrolment
01/07/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Australia

Austria

Canada

Czech Republic

France

Germany

Italy

Spain

Switzerland

United Kingdom

United States of America

Study participating centre
University Medical Centre
Tuebingen
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72074

Sponsor information

Organisation
Genta Incorporated (USA)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Genta Incorporated (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2006	14/02/2019	Yes	No